associated with the COMPAT method described above. For example, the COMPACT device may also perform functions associated with stimulating and measuring a pain response, such as pain threshold or pain tolerance, of a patent.").

Applicant has also amended the specification as suggested by the Examiner whereby the issued patent number for prior application 09/453,770 has been included.

The Invention

The current invention provides methods and interface platforms effective for implementing pain monitoring methods for delivering pain questionnaires to patients at periodic, preferably regular (time settable), intervals. The methods and interface platforms may harvest analgesic drug data from nurses attending the patients, and may provide simple statistical analysis of collected data useful both at the bedside and at central base-stations. The methods and interface platforms may provide additional functions based on analysis of patient pain data. The devices and methods developed will greatly improve responsive pain therapy in pain-suffering patients and will additionally provide a centralized documentation method that will meet JCAHO guidelines.

The current invention provides a Computerized Pain Assessment Tool, called the COMPAT method or the COMPAT software herein, and hardware, called the COMPAT device herein, that runs the COMPAT software. The current invention provides a COMPAT system, also called a COMPAT patient pain management system herein, that comprises the COMPAT device running the COMPAT software as well as a data processor. The COMPAT device may include the data processor, and therefore, in certain embodiments, the COMPAT device is the COMPAT system.

The COMPAT software, COMPAT system, and COMPAT device may be used to assess a patient's subjective pain state at regular, settable, intervals following surgery or other procedure or in response to pain-relieving drugs. The COMPAT device may be a software-driven Pain Questionnaire resident on a touch-screen computer interface. In certain embodiments, it administers any, or all,

of four questions to the pain patient: two visual analog (Pain and Mood) and two category scales (Pain Severity and Pain Relief). The COMPAT device may be equipped with a 'Nurse Input' screen where the caregiver can record drugs, doses and times administered, may provide for the entry of behavioral and 'vital signs' observations in addition, and a Physician Review screen, which presents a graphical history of patient and nurse annotations. The methods and interface platforms may harvest analgesic drug data from nurses attending the patients, and may provide simple statistical analysis of collected data useful both at the bedside and at central base-stations. The methods and interface platforms may provide additional functions based on analysis of patient pain data. The devices and methods developed will greatly improve responsive pain therapy in pain-suffering patients and will additionally provide a centralized documentation method that will meet JCAHO guidelines.

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observations in addition, and a Physician Review screen, which presents a graphical history of patient and nurse annotations.

Allowable Subject Matter

The Examiner indicated that claim 9, if rewritten in independent form, would be allowable. The Applicant has amended claim 9 in independent form to include all limitations of original claim 1 from which original claim 9 depended. Applicant respectfully requests allowance of claim 9.

Objection to Specification

As suggested by the Examiner, Applicant has amended the first paragraph of the specification by inserting "now Patent 6,248,079."

Applicant respectfully requests that this objection be withdrawn.

Rejection Under 35 U.S.C. §112

Claims 11, 18, and 19 have been rejected under 35 U.S.C. §112 as being indefinite. The Examiner indicated that it is "unclear how a dolorimeter can act as a patient communication device."

Applicant has amended claims 11 and 18 to require that the "patient communication device includes a heat beam dolorimeter" rather than "the patient communication device is a heat beam dolorimeter."

Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. §102

(1) Claims 1-4, 6-8, 12-14, and 17 have been rejected under 35 U.S.C §102 as being unpatentable over Iliff (U.S. Patent 5,660,176). According to the Examiner, Iliff teaches "a system and method that uses a computer or telephone network to communicate with the patient . . . [which asks] questions concerning pain, such as chest or pain or head injuries . . . [wherein] the answers are processed and results are generated. Consultations are repeated at different times . . . [and] a pain scale is implemented."

Applicant respectfully disagrees. The present invention as defined in claim 1 and dependent claims 2-4 and 6-8 provides a method for assessing patient pain in real time so as to met the requirements of regulations governing hospital practice promulgated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Specifically, claim 1 provides a method for monitoring pain of a patient, said method comprising: a) providing a patient communication device; b) providing a data processor capable of communicating with the patient communication device; c) delivering a pain questionnaire to the patient at each of a series of time points using the patient communication device to generate pain questionnaire results; d) communicating the pain questionnaire results to the data processor; and e) processing the pain questionnaire results using the data processor, thereby monitoring the pain of a patient. Similarly, independent claim 12 (along with dependent claims 13-14 and 17) relates to a patient pain management system.

Iliff does not teach or suggest a system for **monitoring the pain** of a patient. Rather, Iliff provides a method for providing diagnostic and treatment advice to the general public over a telephone network. Col. 1, lines 15-20. Indeed, the Iliff system is simply a computerized medical knowledge system wherein a patient seeking medial advice calls into the network and answers a series of questions concerning his or her symptoms and, assuming the specific medical problem of the patient has been programed into the computer and that the patient's symptoms are typical of the specific medical problem. This system allows a patent to utilize a computer to provide a detailed medical history without having a face-to-fact interaction with a doctor. Of course, like any medical history, questions concerning pain will be involved. This system does not, however, teach or suggest a system whereby patient pain is **monitored so that appropriate actions can be taken to alleviate and/or control that pain**. Moreover, the questions in Iliff concerning pain appear to relate to the occurrence of pain (i.e., chest pain; col. 38, line 58) and/or freqency of pain (i.e., number of headaches per month; col. 38, lines 35-40) only to the extent they are necessary to provide diagnostic and treatment advice.

Clearly Iliff does not anticipate or render obvious the present invention.

Applicant respectfully requests that this rejection be withdrawn.

(2) Claims 1, 11, 12, and 18 have been rejected under 35 U.S.C §102 as being unpatentable over Nenov (U.S. Patent 6,426,480). According to the Examiner, Nenov provides "a system and method for using a computer ot obtain a Glasgow coma score . . . [wherein] a pain questionnaire is administered . . . [and] various types of pain stimulators are taught."

Applicant respectfully disagrees. The present invention as defined in claim 1 provides a method for assessing patient pain in real time so as to met the requirements of regulations governing hospital practice promulgated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Specifically, claim 1 provides a method for monitoring pain of a patient, said method comprising: a) providing a patient communication device; b) providing a data processor capable of communicating with the patient communication device; c) delivering a pain questionnaire to the patient at each of a series of time points using the patient communication device to generate pain questionnaire results; d) communicating the pain questionnaire results to the data processor; and e) processing the pain questionnaire results using the data processor, thereby monitoring the pain of a patient. Similarly, independent claim 12 relates to a patient pain management system.

Nevov teaches a system for computerized automated acquisition of the Glasgow Coma Score for **quantifying levels of consciousness** following traumatic brain injury. This system relies on three components – that is, eye opening, motor response, and verbal response. Nevov does not teach or suggest a pain management or monitoring system as provided by the present invention. A method for determining the level of consciousness following traumatic pain injury does not teach or suggest the pain management or monitoring system as provided by the present invention.

The Examiner suggests that Nevov provides "a pain questionnaire" and cites Col. 1, lines 44-57 as support. Applicant respectfully disagrees. The portion cited by the Examiner is related to scoring of the motor response component of the Glasgow Coma Score. The portion cited by the Examiner is reproduced below:

> "The motor response is scored on a scale from 1 to 6. A maximum score of 6 is assigned to a patient capable of obeying verbal commands such as 'Show me two fingers'. If the patient does not react to verbal commands, but can localize painful stimuli by moving his or her arm toward the pain source in an attempt to remove the irritant, he or she will receive a score of 5. A patient only capable of a withdrawal response (a reflexive non-localizing movement) is assigned a score of 4. A score of 3 is given to an abnormal flexion response in which the arms are flexed at the elbows. If the motor response is an abnormal rigid extension ('brain stem level') the score is 2. A minimum score of 1 is assigned to a patient who produces no motor response to verbal or pain stimulus."

As one of ordinary skill in the art realized, this does not provide or suggest "a pain questionnaire" as required in the present invention. Nevov cannot teach or suggest a pain management or monitoring system as provided by the present invention.

Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. §103

(1) Claims 1, 3, and 5 have been rejected under 35 U.S.C. §103 as being obvious over Peterson et al. (U.S. Patent 6,241,704) in view of Iliff (U.S. Patent 5,660,176). Applicant respectfully disagrees.

Peterson et al. relates to a menu driven reprogammable drug pump system. According to the Examiner, Peterson et al. provides "a mode where a patient answers questions" (cites Abstract and col. 26, lines 10-15). Applicant respectfully disagrees and respectfully submits that Peterson et al. does not provide or suggest "a mode where a patient answers questions." The portions relied upon by the Examiner for this "mode" are provided as follows:

> "A menu driven reprogrammable drug pump is provided with a memory, such as flash memory, a display, a keyboard, and a communications port to allow a generic pump to be programmed with a desired pump application (therapy) program and patient specific settings. Programming and data transfer with another pump or a computer to and from the patient pump is by the communications port that allows local and/or remote communications with the pump. Flash memory stores the pump application program during use." Abstract.

"Various functions are anticipated for each of the keys on each pump 100, 200. Each key has at least one function. Examples of potential functions of the different keys include:

1) A NEXT SCREEN key to move through the various screens by running a next screen program;

2) An ENTER/CLEAR key;

3) **AN UP ARROW key and a DOWN ARROW key for paging through what is displayed on the screen with a highlight bar, responding to YES/NO questions, or to page through numeric values to highlight and/or display the desired value;**

4) A PRIME key to run a pump prime program to prime the pump;

5) A START/STOP key for operating a pump start program and a pump stop program;

6) A LOCK key for providing access control to the processor through an access program;

7) A DOSE key to run a patient pump control program for permitting patient control of the pumping mechanism;

8) A HELP key for providing help information on the display." Col. 26, lines 3-25 (specific portion cited by Examiner is indicated in bold).

Applicant does not believe that any of these portions, or other portions, of Peterson et al. teach or suggest "a mode where a patient answers questions" or a pain questionnaire. Moreover, Peterson et al. does not correct the deficiencies of Iliff (which are detailed above and are hereby incorporated by reference).

As noted above, Iliff provides a method for providing diagnostic and treatment advice to the general public over a telephone network. It is not even clear what type of system one would obtain by combining the system of Iliff for providing diagnostic and treatment advice over a telephone network with the computerized pump system of Peterson et al. It is clear, however, that one would not obtain the present pain management system.

One of ordinary skill in the art would not consider the present invention obvious in view of the cited references. Applicants respectfully requests that this rejection be withdrawn.

(2) Claims 10, 15, and 16 have been rejected under 35 U.S.C. §103 as being obvious over Iliff (U.S. Patent 5,660,176). Applicant respectfully disagrees.

As noted above, Iliff does not teach or suggest a system for **monitoring th pain** of a patient. Rather, Iliff provides a method for providing diagnostic and

treatment advice to the general public over a telephone network. Col. 1, lines 15-20. Indeed, the Iliff system is simply a computerized medical knowledge system wherein a patient seeking medial advice calls into the network and answers a series of questions concerning his or her symptoms and, assuming the specific medical problem of the patient has been programed into the computer and that the patient's symptoms are typical of the specific medical problem. This system allows a patent to utilize a computer to provide a detailed medical history without having a face-to-fact interaction with a doctor. Of course, like any medical history, questions concerning pain will be involved. This system does not, however, teach or suggest a system whereby patient pain is **monitored so that appropriate actions can be taken to alleviate and/or control that pain**. Moreover, the questions in Iliff concerning pain appear to relate to the occurrence of pain (i.e., chest pain; col. 38, line 58) and/or freqency of pain (i.e., number of headaches per month; col. 38, lines 35-40) only to the extent they are necessary to provide diagnostic and treatment advice.

Clearly Iliff does not anticipate or render obvious the present invention. Applicant respectfully requests that this rejection be withdrawn.

(3) Claim 19 has been rejected under 35 U.S.C. §103 as being obvious over Nenov (U.S. Patent 6,426,480). Applicants respectfully disagree.

As noted above, Nevov teaches a system for computerized automated acquisition of the Glasgow Coma Score for **quantifying levels of consciousness** following traumatic brain injury. This system relies on three components – that is, eye opening, motor response, and verbal response. Nevov does not teach or suggest a pain management or monitoring system as provided by the present invention. A method for determining the level of consciousness following traumatic pain injury does not teach or suggest the pain management or monitoring system as provided by the present invention.

The Examiner suggests that Nevov provides "a pain questionnaire" and cites Col. 1, lines 44-57 as support. Applicant respectfully disagrees. The portion cited

by the Examiner is related to scoring of the motor response component of the Glasgow Coma Score. The portion cited by the Examiner is reproduced below:

> "The motor response is scored on a scale from 1 to 6. A maximum score of 6 is assigned to a patient capable of obeying verbal commands such as 'Show me two fingers'. If the patient does not react to verbal commands, but can localize painful stimuli by moving his or her arm toward the pain source in an attempt to remove the irritant, he or she will receive a score of 5. A patient only capable of a withdrawal response (a reflexive non-localizing movement) is assigned a score of 4. A score of 3 is given to an abnormal flexion response in which the arms are flexed at the elbows. If the motor response is an abnormal rigid extension ('brain stem level') the score is 2. A minimum score of 1 is assigned to a patient who produces no motor response to verbal or pain stimulus."

As one of ordinary skill in the art realized, this does not provide or suggest "a pain questionnaire" as required in the present invention. Nevov cannot not teach or suggest a pain management or monitoring system as provided by the present invention.

The Examiner did note that the reference does not teach a dolorimeter utilizing a sonar ranging senor as specifically required by claim 19. The Examiner noted that "it would have been an obvious matter of design choice to modify the system and method of Nenov by using a sonar ranging sensor since Applicant has not disclosed that using such a sensor solves any stated problem or is fo rany particular purpose and it appears that the system/method would perform equally well with any type of pain stimulator." The Examiner appears to be using Applicants own teachings to provide the sonar ranging sensor and to include it in the system. The Examiner knows that this is improper. See, for example, W. L. Gore & Assoc., Inc. v. Garlock, Inc., 220 USPQ 303, 312-13 ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."); In re Fine, 5 USPQ.2d 1596, 1600 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.").

Applicant respectfully requests that this rejection be withdrawn.

(4) Claim 20 has been rejected under 35 U.S.C. §103 as being obvious over Iliff (U.S. Patent 5,660,176). Applicants respectfully disagree.

As noted above, Iliff does not teach or suggest a system for **monitoring the pain** of a patient. Rather, Iliff provides a method for providing diagnostic and treatment advice to the general public over a telephone network. Col. 1, lines 15-20. Indeed, the Iliff system is simply a computerized medical knowledge system wherein a patient seeking medial advice calls into the network and answers a series of questions concerning his or her symptoms and, assuming the specific medical problem of the patient has been programed into the computer and that the patient's symptoms are typical of the specific medical problem. This system allows a patent to utilize a computer to provide a detailed medical history without having a face-to-fact interaction with a doctor. Of course, like any medical history, questions concerning pain will be involved. This system does not, however, teach or suggest a system whereby patient pain is **monitored so that appropriate actions can be taken to alleviate and/or control that pain**. Moreover, the questions in Iliff concerning pain appear to relate to the occurrence of pain (i.e., chest pain; col. 38, line 58) and/or freqency of pain (i.e., number of headaches per month; col. 38, lines 35-40) only to the extent they are necessary to provide diagnostic and treatment advice.

Clearly Iliff does not anticipate or render obvious the present invention.

Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicants respectfully request that the Examiner allow pending claims 1-20 and pass this Application to issue.

If the Examiner believes that a telephonic or personal interview would be helpful to terminate any issues which may remain in the prosecution of the Application, the Examiner is requested to telephone Applicants' attorney at the telephone number set forth herein below.

The Commissioner is hereby authorized to charge any additional fees which may be required in the Application to Deposit Account No. 06-1135.

Respectfully submitted

FITCH, EVEN, TABIN & FLANNERY

By:

Richard A. Kaba
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February 12, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: **Lipman**

Application No.: 09/841,795

Filed: April 24, 2001

Title: COMPREHENSIVE PAIN ASSESSMENT SYSTEMS AND METHODS

Group Art Unit: 3736

Examiner: David J. McCrosky

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this date.

2/12/03
Date

Registration No. 30,562
Attorney for Applicant(s)

APPENDIX TO AMENDMENT PURSUANT TO 37 CFR 1.121 (c)(1)(ii)

Hon. Commissioner of Patents
and Trademarks
ATTENTION: Assistant Commissioner
For Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.121 as amended effective 7 November 2000, Applicants present herewith marked-up text of the claims of this application as amended by the foregoing amendment:

9. (Once amended) [The method of claim 1] A method for monitoring pain of a patient, said method comprising:

B2

a) providing a patient communication device;

b) providing a data processor capable of communicating with the patient communication device;

c) delivering a pain questionnaire to the patient at each of a series of time points using the patient communication device to generate pain questionnaire results;

B2 d) communicating the pain questionnaire results to the data processor; and

e) processing the pain questionnaire results using the data processor, thereby monitoring the pain of a patient,

wherein the pain questionnaire comprises a Visual Pain Analog Scale, a Visual Mood Analog Scale, a Pain Severity Scale and a Pain Relief Scale.

B3 11. (Once amended) The method of claim 1, wherein the patient communication device [is] includes a heat beam dolorimeter.

B4 18. (Once amended) The system of claim 12, wherein the patient communication device [is] includes a heat beam dolorimeter.

Respectfully submitted,

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